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Judge Sean D. Jordan
U.S. District Court for the Eastern District of Texas
Sherman Division
7940 Preston Road, Suite 111
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RE: Brief in support of patients represented in complaint for declaratory relief in civil action number 4:20-cv-00817

Dear Honorable Judge Sean D. Jordan:

I write to you on behalf of all my patients represented in the civil complaint. My interests reside in the well-being of my patients throughout Northwest Indiana who have filed prescriptions for medications classified by the Drug Enforcement Agency (DEA) as controlled substances, and were either denied their medically necessary prescriptions or faced undue discrimination while filing their prescriptions – either explicitly or implicitly – due to their physical appearance, their particular mannerisms, or their medical history.

And I write to ensure that the clarifications that come from this civil action address the undue burdens imposed upon physicians and patients who are and have been disproportionately affected by the opioid epidemic – ensuring the clarifications recognize that law adjudicating healthcare cannot be restrictive in nature; rather, it must be affirmative in nature, maintaining a Madisonian balance between individual liberties and responsibilities, and the common good and social welfare.

During the COVID-19 pandemic, we learned firsthand of the Constitutional violations that arise when governments establish ad hoc rules and mandates purportedly in the name of public safety. A trend Supreme Court Justice Alito alluded to when he said COVID-19 restrictions highlight a disturbing trend of 'lawmaking by executive fiat'.

But the COVID-19 pandemic simply made apparent a trend that was already present during the opioid epidemic – that government encroachment into healthcare has led to a fundamental violation of civil liberties, placing undue burdens upon select, targeted individuals – using public perception to justify unconstitutional enforcement and retroactive reinterpretation of law against select minority peoples and professions.

A premonition highlighted early in our nation's history by French philosopher, Alexis de Tocqueville when he cautioned that America should be weary of the, 'tyranny of the majority'.

Healthcare laws that are fundamentally restrictive are fundamentally unconstitutional because they place undue burdens on select individuals. The Declaration of Independence affirms certain 'unalienable rights' to all Americans, which include, 'life, liberty and the pursuit of happiness'.

And it can be construed that these rights include healthcare. Therefore healthcare is not a right in the absolute sense – but, as many legal scholars have argued, a positive right. Which means it is a right that comes with commensurate

responsibilities and obligations, and the right afforded depends upon the responsibilities and obligations fulfilled. Hence healthcare law adjudicating healthcare rights should be constructed as an affirmative law, maintaining a Madisonian balance between individual liberties and common good.

But the Controlled Substance Act (CSA), Title Code 21 is a fundamentally restrictive law. And restrictive laws that attempt to regulate positive rights will inevitably conflict with the Constitution.

As you review the case before you, I humbly request that you adhere to the Constitutional principles underlying the Madisonian balance of affirmative law, and analyze the inherent limitations in the CSA that warrant clarification through the following frameworks – standardizing your medical jurisprudence.

Elemental & Essential Analysis of Law

Healthcare is unavoidably complex, and most healthcare statutes are constructed as a series of definitions, attempting to characterize these complex concepts. Which can be seen as an essential analysis of law – adjudicating criminality through the multiple attributes that define the essence of the complex concept.

But inconsistencies in how much to weigh each individual attribute within the core essence of a statute has led to legal interpretations that overweigh a limited number of individual attributes relative to the overall essence of the law – creating legal interpretations that conflate an elemental analysis of

specific aspects of the law to be an essential understanding of the law in its entirety.

Flawed thinking the Roman philosopher Plutarch encapsulates in his syllogism of the lost dog searching for his master: a lost dog travels down a road he is sure his master has traveled based on sensing the master's scent, and soon encounters a three-tiered fork in the road; the dog takes the first path but returns after losing the scent, and then takes the second path only to return again after losing the scent again; the dog then races down the third path sure that is the path the master took because he lost the scent on the first two paths, only to find his master is not on that path either.

The dog, in this syllogism, never once considers that the master is not on any of the paths. A misunderstanding that affects many prominent healthcare laws in this country. The Affordable Care Act was believed to be entirely dependent upon a tax penalty mandate, imposed upon individuals who did not obtain insurance. But the law continued to be followed even after the mandate was severed, and in certain parts of the country, a greater percentage of the population obtained insurance through ACA enabled markets after the mandate was dropped – questioning the perceived severability of the mandate relative to the overall essence of the law.

This is a critical understanding I hope you recognize when analyzing the CSA. How has overweighing or recontextualizing (ex post facto) specific aspects of the law violated the overall essence and intent of the law?

The US Court of Appeals for the Ninth Circuit and the Supreme Court have declared that the prosecution of healthcare providers under the CSA must prove that the defendant, "acted with intent to distribute the drugs and with intent to distribute them outside the course of professional practice," suggesting that intent, or mens rea, must be established with respect to the nature of the defendant's failure to abide by professional norms. The mens rea requirement additionally states that, "it shall be unlawful for any person knowingly … to distribute … a controlled substance … outside the course of professional practice".

The most important words included in the mens rea requirement being 'intent' and 'knowingly'. And if the mens rea standard is abandoned, the guiding compass that balances the various attributes within the essence of the statute are lost.

Instead you will find elemental frameworks selectively emphasizing specific actions and retroactively reinterpreting clinical behavior to be criminal – overweighing specific attributes in isolation – attempting to present an elemental analysis of law that should be essential in nature – while failing to account for the preponderance of evidence in totality. In other words, the law,

when interpreted to the point of distorting the underlying clinical behavior, fails to balance the intent of the law with a consistent understanding of medically appropriate clinical behavior.

Prospective & Retroactive Understanding of Uncertainty

Clinical decision-making and behavior, as author Malcolm Gladwell describes, is "full of ambiguity and complexity", and nearly impossible to define definitively without oversimplifying certain aspects of particular decisions, inevitably producing a certain vagueness in legal interpretations.

But the vagueness that may appear from simplifying patient behavior can be minimized by understanding the differences in uncertainty that arise from a clinical perspective relative to a legal perspective.

In the clinical world, you think associatively and prospectively, aggregating clinical data in real time to identify the most likely clinical scenario. In the legal world, you think linearly and retroactively, piecing together evidence after the fact to construct an argument. Information that is available after the fact is often not available in real-time.

But more importantly, what is considered important in real-time may be retroactively recontextualized to be more or less important afterwards. You will find many actions and behaviors characterized through the proverbial 'should have known' and 'how likely it is to have known' in the upcoming legal arguments – which are nothing more than differing perspectives in how

to adjudicate uncertainty. And reflects a critical limitation in the CSA, which affects the Constitutionality of the law depending on how the law in interpreted.

The CSA fails to account for the differences in how uncertainty manifests in the clinical and legal world. When confronted with this issue in the past, previous legal interpretations opted to evaluate actions that are legally permissible or not permissible through a vaguely defined phrase, 'bonafide medical practice', that has not been updated in nearly a half-century. But this phrase has been inconsistently applied when approximating the dynamic, prospective nature of medical uncertainty into a static, retroactive interpretation of legal uncertainty.

As a result, criminality depends on whether the interpretation of the clinical behavior fits within the presumed description of medically appropriate behavior as defined by the investigating DEA officer – and if the descriptions do not match, then the law has been violated.

If a physician prescribes a controlled substance over the course of clinical care as part of a 'bonafide medical practice' then the prescription is valid, if not, then the law has been violated. If a patient obtains a controlled substance to relieve the 'suffering incident to an addiction', then the prescription is valid, but if a patient obtains it to cater to the 'cravings of an addict', then the law has been violated – but to describe sufferings or cravings

in a patient is a matter of interpretation, that can easily change over time and easily differ depending on who is interpreting the behavior.

As a patient who fails to receive medical care can easily become an addict – just as an addict who receives proper medical care can become a patient with a substance use dependency. The very attributes that have been used to define the essence of the CSA fail to define the essence of pain management and addiction medicine – because the law fails to understand the different types of uncertainty that exist between the clinical and legal world.

When interpreting the law, establish a consistent reference standard to approach uncertainty from both perspectives, and be sure not to allow any one attribute to overwhelm the multifaceted uncertainty that will form the foundation of your jurisprudence. Create a doubt schematization framework that standardizes how uncertainty is addressed and progressively minimized from a dynamic, clinical perspective into an eventual static, legal perspective.

Failing to do so will introduce primarily inductive arguments that are more strong than valid, probabilistic in nature, and subject to change depending on whether the suppressed premise underlying the inductive argument is elucidated within the proper clinical context. You will find yourself mired in haze of doubt estimating the intent of a patient, a pharmacist, or a physician without an objective standard through which you can compare.

> I humbly request that you establish a framework that ensures the essence of the CSA represents the essence of pain management and addiction medicine, as we currently understand these two medical fields. That ensures the individual actions evaluated through the lens of the law are simultaneously viewed from the perspective of clinical decision-making – weighing aspects of both types of uncertainty in your jurisprudence.

A correctly designed framework for medical jurisprudence will balance the elemental and essential frameworks of law and the underlying uncertainties. And, accordingly, will account for the law of unintended consequences – the secondary and tertiary effects of legal interpretation that sway the distribution of burdens – not only from one set of individuals to another, but inappropriately distribute the burden of actual risk relative to potential risk.

In law, we perceive the distribution of burdens in terms of individuals or minority populations who are disenfranchised in some capacity due to a law or the interpretation of a law. But in healthcare, the distribution of burdens must account for actual risks and potential risks that may occur when implementing a law in clinical practice – and evenly distribute the clinical burdens with the clinical risks, both actual and potential, among all patients, pharmacists, and physicians.

For example, in deciding whether a patient merits a prescription, the physician must evaluate the patient's clinical need for the medications with the risk of abuse. That is a straightforward legal rubric – but woefully inadequate in accounting for

all the clinical consequences. The physician must also evaluate whether the patient poses a potential risk of diversion – meaning the patient may not abuse the medication, but the patient may not take the necessary precautions to prevent others, family and friends, from abusing the medication.

That is a potential risk that the physician may not realistically be able to address, but a risk that physicians are still liable for as per recent interpretations of the CSA. As a result, physicians have drastically reduced the amount of opioid prescriptions in response to being additionally burdened with the added potential risk – which has been portrayed as an apparent victory in the eyes of law enforcement.

But in reducing the number of opioids prescribed, many patients with legitimate medical needs now face an unforeseen, undue burden of not being able to receive medications for their chronic medical conditions. Furthermore, numerous clinical studies have demonstrated little to no correlation in opioid abuse mortality and the total number of opioids prescribed. But for law enforcement, the potential risk of diversion supersedes the actual clinical risk to patients that comes from poor clinical care.

The pretense of mitigating a potential risk placed undue burdens upon patients, and failed to properly address all the consequences of criminalizing the opioid epidemic in such an aggressive manner, which only exacerbated poor clinical care among physicians too scared to prescribe clinically necessary medications – creating

undue burdens on physicians seeking to practice earnestly, and to patients with chronic medical conditions.

Therefore, I humbly request that you analyze actual and potential clinical risk and the distributions of clinical burdens through multiple layers of consequences – the most immediate, apparent consequences, and the unintended, insidious consequences that have proven to be just as considerable.

The simplest, most consistent manner to address the myriad of consequences is by stress-testing the aforementioned frameworks by actively simulating patient decision-making – implementing principles of game theory to assess the Constitutionality of a proposed legal interpretation within a range of predefined clinical scenarios.

In game theory, individuals make choices based upon the nature of the game being played. In zero sum games, individuals have opposing interests, and in non-zero sum games, individuals have some interests in common and some not – what is called mixed motives. When individuals agree on a plan of action, the game is called cooperative, and when individuals cannot agree, the game is called noncooperative. The behavior of the players, and the decisions made, are influenced by the nature of the game.

The most common introductory example of game theory is the prisoner's dilemma, a noncooperative game in which two men are imprisoned in separate jail cells, and told that if neither confesses, both will receive a mild sentence; but if one confesses

and one does not, the one who confesses will be freed while the other will receive a severe sentence; but if both confess, they both will receive a moderate sentence.

Ideally neither should confess, but by pursuing their own interests, both prisoners confess and receive moderate sentences. The example summarizes the conflict between the interests of individuals and what is in the best interest of the group.

A premise directly applicable to how Constitutionally appropriate interpretations of the CSA must balance individual patient rights and liberties with the perceived common good.

Healthcare is a non-zero sum game with varying degrees of cooperation and noncooperation. To determine whether a specific action or decision constitutes criminal behavior, define the behavior within the context of a non-zero sum game, and ascertain whether clinically appropriate behavior would have been cooperative or noncooperative in that scenario. Study the behavioral tendencies of physicians, pharmacists, and patients within this context, and in response to one another, to ascertain whether true criminal intent, mens rea, influences the behavior in question.

As you review the evidence presented in the case, you will find my words prescient and an indispensable guide in your jurisprudence – and you will have to decide whether healthcare is a right, and if you believe it is a right, then you are likely to agree that it is a positive right – implying that the interactions, decisions, and behaviors of patients, physicians, and pharmacists must be evaluated against a

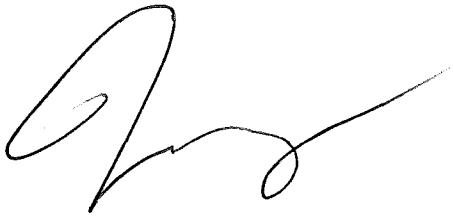
reference standard that adjudicates individual actions within a broader, clinical context.

A Madisonian balance equating rights and liberties afforded with civic duties and responsibilities fulfilled.

It is my sincere hope that you see the passion and dedication I have for my patients through the words I have written. The opioid epidemic has taken countless lives and affected innumerable Americans, both directly and indirectly – and it has affected me personally both from a medical and legal standpoint.

But through my pain, I have gained wisdom, which I have shared in hopes that you are now able to recognize, and can now deliberate upon the full clinical impact of the case before you.

Respectfully,



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Amicus Curiae Brief

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Prepared for

Judge Sean D. Jordan

Of the

U.S. District Court for the Eastern District of Texas

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Prepared by: Dr. Jay K Joshi

November 14, 2020